

**Docket Number: 01P-0169**

8648 '01 JUN 18 P154

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FDA  
Dockets Management Branch  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852

To Whom It May Concern:

As one of the countless IBS sufferers who were helped immeasurably by the GlaxoSmithKline drug Lotronex, I pray daily that Lotronex will be put back on the market soon.

For more than 13 years, I have suffered from Irritable Bowel Syndrome. I have spent my entire adult life passing the dinner hour in the ladies room, leaving social occasions early, spending vacations and work travel outings in my hotel room bathroom and missing many events that were important to me and to the people I love, all thanks to the symptoms of IBS.

Needless to say, my ill health spoiled many events for my friends and family as well as for myself. Thankfully, I am one of the lucky ones who have usually had ready access to a private bathroom at work.

I have tried many medications, both prescription and over-the-counter, to no avail. I have put my body through various diets that are thought to improve the symptoms of IBS...one of which made me sicker than ever while others did nothing but deprive me of the proper nutrition that a person's body needs.

In addition, I have tried biofeedback, relaxation tapes, medications not meant for IBS and herbal therapies. While none of my experimentations made me any better, I do count myself lucky that I did not do irreparable damage to my health in my quest to find a cure.

Through years of frustration, I had finally given up on trying to find any help for my symptoms (urgent and explosive diarrhea, excruciating stomach pains, all-consuming nausea and a general malaise).

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But after the birth of my daughter, I realized that my IBS was not only controlling my life, but dictating hers as well. No spontaneous trips to the park for us. Trips to the pediatrician were spent praying that I wouldn't need to rush to the bathroom while my daughter needed me. "Mommy & Me" classes were missed as often as we were able to show up.

I could go on and on, but I'm sure you get the idea.

That's when I decided to seek help from my doctor one more time. Imagine the relief I felt when the Lotronex my doctor prescribed *actually worked*. Gone were each and every symptom of my disorder. I felt healthy and free for the first time in my adult life.

That freedom was soon yanked away when Lotronex was removed from the market. Getting sick again was worse than before, because now I could remember what it was to feel healthy. It seems like the cruelest hoax to have my health restored to me only to have my cure taken away.

I believe that doctors and patients should be better informed about the risks involved with Lotronex as well as proper dosage.

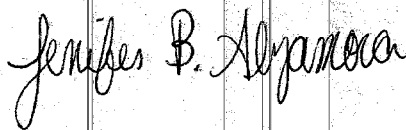
However, I know that for me, the benefits of Lotronex outweigh the risks. This is true for many others who have already taken Lotronex, as well.

Under current guidelines, I am legally allowed to stock my medicine cabinet with countless drugs that could possibly, under the right conditions, have deadly side effects – including aspirin. There is room in *my* medicine cabinet for Lotronex. Please don't deny me the right to use it.

I've read much criticism of the FDA lately from lazy journalists (or their editors) and advocates of Public Citizen, who prefer to use only old data and sensationalist opinions.

I trust that IBS sufferers can be assured that you will not be swayed by biased media reporting, but will keep the good of each individual patient foremost in your mind.

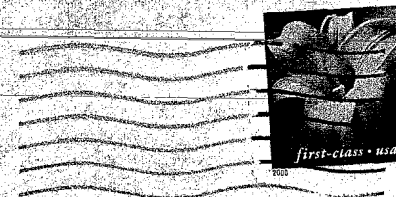
Sincerely,

A handwritten signature in cursive script that reads "Jenifer B. Alzamora".

Jenifer B. Alzamora

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